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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SRIVASTAVA, KAILASH C	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/978,344	DENNIS ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-42* is/are pending in the application.

4a) Of the above claim(s) *33-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *121701&10102*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

CLAIMS STATUS

1. Claims 21-42 are pending.

Restriction/Election

2. Applicants' election with traverse of Group I, Claims 21-32 filed 02 July 2004 is acknowledged and entered. Applicants' traversal is on the grounds that the claims 21-32 engrouped as invention of group I drawn to a composition and Claims 33-42 engrouped as invention of Group II drawn to a method can be searched without any hardship to the Examiner because the "subject matter of the required search is sufficiently small and closely related"". This is not found persuasive because of the reasons of record on pages 2-3 in Office Action mailed 18 June 2004. In addition, the search for each of the distinct inventions of Groups I-II is not co-extensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the condition for patentability is different in each case. Thus, it will be an undue burden to examine all of the inventive Groups in one application. Therefore, the restriction requirement is still deemed proper and is made FINAL.

Accordingly, Claims 33-42 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR §1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims cited *supra* be canceled in response to this Office action to expedite prosecution.

3. Claims 21-32 are examined on merits.

Information Disclosure Statement

4. Applicants' Information Disclosures (i.e., IDSs) filed 11 December 2001 and 01 October 2002 have been made of record and considered.

Priority

5. Applicants' claim for domestic priority under 35 U.S.C. §120 is acknowledged.

Claim Rejections - 35 U.S.C. § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 21, 23-24 and 27-32 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

- Claims 21-32 as written are very confusing, unclear and difficult to understand. Applicants are requested to clearly, concisely and succinctly rewrite the claims in such a manner that the claims clearly indicate the applicants' invention. Applicants are reminded to ensure that no new matter is added while they clearly and succinctly re-write the claims.

- In Claim 23 at Line 1, the phrase "said material is hydrophobic" lacks sufficient antecedent basis because Claim 23 depends from Claim 22, which recites, "particle of Claim 21, wherein said reactive molecules are enzymes".

- The recitation "an oil core" in Claim 24 renders that claim vague, unclear and indefinite, because the metes and bounds for said term are not defined in the claim language. Applicants should clearly define the term, an oil core".

- The recitation "templated pores" in Claim 27 renders that claim vague, unclear and indefinite, because the metes and bounds for said term are not defined in the claim language. Applicants should clearly define the term, "templated pores".

- In Claim 28, the phrases "comprising a hollow tube open at least at one end" at Line 1 bridging with Line 2 and "inside surface of said tubule and said second region comprises a reactive molecule attached to a surface of said tube" beginning at Line 4 and ending at Line 5 lack sufficient antecedent basis because Claim 21 from which Claim 28 depends does not recite any Tube or tubule or surface thereof.

All other claims depend directly or indirectly from the rejected claims (e.g., Claim 21) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections - 35 U.S.C. § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 21 and 23-26 are rejected under 35 U.S.C. §102(b) as anticipated by Ribier et al. (U.S. patent 5,993,881).

Claims recite a particle comprised of reactive molecules that transform a toxic compound to innocuous material, said reactive molecules present in one region of particle are in contact with the second region of said particle, wherein said second region comprises a hydrophobic material, e.g., oil or liquid core to partition said toxic compound into the second region and further the said material is encapsulated in a porous inorganic or polymer shell.

Ribier et al. teach a composition comprising nanoparticles of one or more non-biodegradable polymers encapsulating an oily phase containing an active ingredient with prolonged cosmetic or pharmaceutical activity (e.g., capturing free radicals in skin or epidermis). The active ingredient present in the oil is encapsulated within the nanoparticle (Abstract, Lines 1-8, Column 1, Lines 58-62) and when said nanoparticle is topically applied to ski/epidermis, the active ingredient removes the free radical. Note that oil is a liquid. Thus, Ribier inherently teach a particle wherein an oil/liquid containing an active ingredient to remove a toxic material (i.e., free radical) in a subject is encapsulated in a polymer (e.g., polyethylene or styrene alkyl alcohol oligomers, Column 2, Lines 45-67). Note that since the reactive material is contained in the oil/liquid and said liquid is encapsulated, Ribier et al's nano-size particle composition is comprised of two separate regions that are in contact with each other.

Therefore, the reference is deemed to anticipate the cited claims.

10. Claims 21-22 and 28-32 are rejected under 35 U.S.C. §102(b) as anticipated by Babich et al. (WO 00/47236). The reference in rejection is made to U.S. Patent 6,395,299 which is equivalent of WO 00/47236).

Claims recite a particle comprised of reactive molecules that transform a toxic compound to innocuous material, said reactive molecule is an enzyme and is present in one region of particle which is in contact with the second region of said particle, wherein said second region comprises a hydrophobic material/liquid to partition said toxic compound into the second region and further the said material is encapsulated in a porous inorganic or polymer shell. Said particle is a nano-sized particle.

Babich et al. teach sol-gels encapsulating a reaction center, said sol-gels with or without encapsulated enzymes (i.e., a reactive center, e.g., enzyme L-amino acid decarboxylase) are

administered to a subject in need of to convert prodrugs (e.g., L-DOPA) into biologically active agents (e.g., dopamine) to treat for e.g., Parkinson's disease (Abstract, Lines 1-8). Babich et al. further teach that their Sol-gel matrices comprise oxysilane, tetramethyl- or tetraethyl orthosilicate, inorganic oxide, siloxane, and the active agent may be a variety of enzymes (e.g., L-amino acid decarboxylase, oxidoreductases, transferases, hydrolases, isomerase, ligases and the like). Babich et al. also teach that their particle may have a variety of size ranges, e.g., from 1-100nm and morphologies from spherical, cylindrical, tube-like, rectangular etc (Column 33, Lines 50-63; Column 66, Lines 11-18,and 61 to Column 67, Line 6; Column 67, Lines 59-61, Column 68, Lines 67 to Column 69, Line 55). Note that since the reactive material is contained in the liquid and said liquid is encapsulated in another polymer, Babich et al's nanosize particle composition is comprised of two separate regions that are in contact with each other.

Therefore, the reference is deemed to anticipate the cited claims.

Claim Rejections - 35 U.S.C. § 103

11. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> ***A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.***

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § *102*(f) or (g) prior art under 35 U.S.C.§ 103(a).

13. Claims 21-32 are rejected under 35 U.S.C. § 103 (a) as obvious over Ribier et al. (U.S. patent 5,993,831) in view of Babich et al. (WO 00/47236; The reference in rejection is made to U.S. Patent 6,395,299 which is equivalent of WO 00/47236)
and Yang et al (WO 01/17648).

Claims recite a particle comprised of reactive molecules that transform a toxic compound to innocuous material, said reactive molecules present in one region of particle are in contact with the second region of said particle, wherein said second region comprises a hydrophobic material, e.g., oil or liquid core to partition said toxic compound into the second region and further the said material is

encapsulated in a porous inorganic or polymer shell. Furthermore said reactive molecule may also be an enzyme. Said particle is a nano-sized particle.

Teachings from Ribier et al. and Babich et al. have already been discussed *supra*. Their teachings, while disclosing that the preparations, e.g. sol gels are porous and comprise materials containing silica do not clarify the silica component of the composition. Yang et al., clarify that their nanoporous reactive adsorbent incorporates metals, enzymes particles forming continuous and discontinuous phase interspersed with continuous phase of smaller particles and interstitial pores (Abstract, Lines 1-6).

One having ordinary skill in the art at the time of the claimed invention would have been motivated to modify/combine the teachings from Ribier et al. according to beneficial teachings from Babich et al and Yang et al to obtain a nano-size, nanoporous particle comprising a reactive center contained in an oil/liquid/hydrophobic phase, where in said oil/liquid is encapsulated in another polymer (i.e., sol gel or silica-gel) to remove or biotransform toxic materials in a subject to innocuous or beneficial materials (e.g., L-DOPA to dopamine), because each one of the three prior art references teaches a nano-size particle material comprising a reactive center encapsulated in a polymer and said nano-size particle detoxifies a toxic material. Ribier et al. teach a nanosize particle comprising oil/liquid containing an active reagent, wherein said oil is encapsulated in a polymer, Babich et al. teach an enzyme encapsulated in sol-gel, whereas Yang et al. teach a nanoporous particle comprised of enzyme/metal containing adsorbent encapsulated in silica gel. Babich et al. remedy the deficiency of enzyme in the teachings from Ribier et al., whereas Yang et al., remedy the deficiency of clearly teaching the silica component in Ribier et al's nano-size detoxifying particle.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Ribier et al. according to teachings from babich et al. and Yang et al. to obtain a reactive center containing nao-size detoxifying particle to detoxify toxic contaminants in a subject. . Babich et al. remedy the deficiency of enzyme in the teachings from Ribier et al., whereas Yang et al., remedy the deficiency of clearly teaching the silica component in Ribier et al's nano-size detoxifying particle.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

14. No Claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(571) 272-0923

September 30, 2004